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THE CENTER FOR Women's Sexual Health

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the Application of: Joel S. Hochman, et al

Ser. No.: 10/007,393

Filed: October 26, 2001

For: SYSTEM AND METHOD FOR TRANSDUCING, SENSING OR AFFECTING VAGINAL OR BODY CONDITIONS, AND/OR STIMULATING PERINEAL MUSCULATURE AND NERVES USING 2-WAY WIRELESS COMMUNICATIONS

Examiner: Charles A. Marmor

Group: 3736

Commissioner for Patents

PO Box 1450

Alexandria VA 22313

DECLARATION TO SUPPORT THE NON-APPLICABILITY OF THE GUICE PATENT

I, Christopher J. Jayne, MD, declare as follows:

1. I am a Graduate with Honors from Buffalo School of Medicine, Buffalo New York, completed a residency in Obstetrics and Gynecology with Honors at Baylor College of Medicine, Houston Texas. I am Board Certified and a Fellow of the American College of Obstetricians and Gynecologists, and a Certified Sex Counselor by the American Association of Sex Educators Counselors and Therapists. I am the Medical Director of The Center for Women's Sexual Health at the Texas Medical Center in Houston Texas. I am a member of the Clinical Faculty at the Baylor College of Medicine in Houston Texas.
2. I am familiar with the subject matter of the above-identified application. In addition, I have carefully studied U.S. Patent Publication 2002/0010390. Guice, et al.

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3. Based on my knowledge and expertise, I hereby state that one of ordinary skill in the art would not consider the Guice reference when trying to provide a system and method for transducing vaginal conditions, affecting vaginal or body conditions, and stimulating perineal musculature and nerves in humans.

4. In particular, one of ordinary skill in the art would not look to Guice, which is clearly limited to use in animals, for any teaching or suggestion with respect to how to use or configure a device that is intended to be temporarily, i.e. in a non-implanted manner, inserted into a human vagina. As indicated, Guice is clearly limited to use in animals, which is very understandable given the significant anatomical differences between the vaginas of animals, and especially cows, and those of humans. This is supported by FDA standards and regulations and safety concerns that define implants, as will be discussed below. See also 21 CFR Part 1, which discusses FDA regulation of devices to assure their safety and effectiveness, and also 21 CFR 895 with respect to banned devices.

5. Regarding the use of the terms "non-implanted", "implant", and terms derived therefrom, these terms are all terms of the art in our field. Furthermore, with regard to definitions, limitations, etc. for these terms, the devices utilized in our field are regulated by the FDA, especially due to health and safety concerns, since they are medical devices (see, for example, 21 CFR 876.5320 regarding a non-implanted electrical continence device). Therefore, since with respect to such devices we must comply with the FDA Rules, Standards and Regulations, one of ordinary skill in the art in this field would, of course, and does, in the ordinary usage of these terms, understand these terms in a manner fully consistent with the applicable FDA definitions found in Title 21 of the Code of Federal Regulations.

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6. Guice, for example in [0179], makes it clear that his device is adapted to be compressed and then expanded to keep the device in place in an ear canal or other cavity of an animal. Guice even suggests adhesive. A tool, such as pliers, is needed to be able to install and remove the device from the animal. In contrast, the device of the above-identified patent application for Hochman is defined in the claims to be "self-applied" or "self-inserting" by a human subject, which to one of ordinary skill in the art is clearly understood to mean without the use of a tool, such as the pliers required by Guice.

7. In the medical and veterinary fields, the device of the above-identified application of Hochman is not an implant, i.e. has a non-implanted probe. In contrast, the device of Guice would be considered by one of ordinary skill in the art to be an implant, and this is also true under FDA standards (see for example 21 CFR 812.3(d).) Thus, the device of Guice is in no way comparable to the device of the above-identified application, which is temporarily insertable, or self-applicable, by a human subject. Guice itself stresses that his device is a true implant, i.e. is to be implanted, or is an implant, which one of ordinary skill in the art clearly understands to be the opposite of "non-implanted", since if it is to be implanted it cannot be a non-implanted device. The reason for the Guice device being an implant is in large part due to the aforementioned differences in the anatomy of humans and animals, which requires that the device of Guice, in order to be effective, i.e. retained, must be implanted in the animal being monitored; if it were not implanted, it would be expelled upon urination. Furthermore, as mentioned above, also pursuant to FDA standards and definitions, the Guice device is an implant whereas the device of the above-identified application is not, as confirmed by the FDA device approval letter issued to Athena.

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8. In conclusion, the Guice device is entirely unsuitable for human vaginal use, and one of ordinary skill in the art would not consider the Guice reference for any teaching or suggestion with regard to the configuration of a device that is to be temporarily inserted, i.e. non-implanted, into the human vagina, for example because one simply would not consider an implantable animal device when trying to come up with a device for humans that is self-inserted or self-applied by a human subject. Animals cannot self-insert. I respectfully submit that to assert that a device made for a cow's vagina, or ear or any other cavity, would be capable of being inserted into a human vagina is simply not a reasonable interpretation to one of ordinary skill in this art.

9. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful, false statements may jeopardize the validity of this application, the patent which issues thereon, or any patent to which this verified statement is directed.

8/18/05

Christopher J. Jayne, MD, FACOG Date
AASECT Certified Sex Counselor
Medical Director, The Center for Women's
Sexual Health